

Appendix H: Frequently Asked Questions



A health study for oil spill clean-up workers and volunteers

ANSWERS TO YOUR QUESTIONS

What is the GuLF STUDY about?

The GuLF STUDY is the largest health study that has ever been conducted among oil spill clean-up workers and volunteers. The study will learn about potential health effects of the Deepwater Horizon oil spill in the Gulf of Mexico. The study will enroll and follow 55,000 people, including those who did clean-up work and others.

What is the purpose of the GuLF STUDY?

The purpose of the GuLF STUDY is to learn more about any potential health effects of the recent oil spill in the Gulf of Mexico. This study will include both people who were involved in oil spill clean-up and others who did not do clean-up work. Findings from the study will identify health needs of people involved in oil spills and may change public health responses to similar disasters in the future.

Who is running the study?

Researchers at the National Institute of Environmental Health Sciences (NIEHS) are running the study. NIEHS is one of the National Institutes of Health, which is part of the Department of Health and Human Services. The website for the NIEHS is <https://www.niehs.nih.gov>. Dr. Dale Sandler, Chief of the NIEHS Epidemiology Branch, is the study's principal investigator.

Who is enrolling participants and collecting data for NIEHS?

SRA International, a professional company that specializes in health research, works closely with the NIEHS to recruit and enroll people in the study. They collect data and manage the day-to-day activities of the study. More information about SRA can be found at <http://www.sra.com>.

Is BP involved with the study in any way?

BP is not involved in this study. They were not involved in the design of the study and play no role in carrying it out or analyzing the study data. BP has donated money to the National Institutes of Health to fund health research related to the oil spill. Some of the money that BP donated will be used for the GuLF STUDY. But, most of the money for the study comes from the NIH directly.

Why is the GuLF STUDY important? What will it tell us?

More than 150,000 people did work related to clean-up of the oil spill in the Gulf of Mexico. This study will learn how different aspects of oil-spill clean-up may impact future health. The study can also learn how stress and job loss because of the oil spill can affect health, including mental health. The findings from the study may influence long-term public health responses in Gulf communities or responses to other oil spills in the future.

Why study people who were not directly involved in clean-up activities?

Even people not directly involved in oil spill clean-up may have been affected by the spill. Furthermore, by comparing workers doing specific clean up jobs to others who did not do those jobs, we can learn if health problems are occurring at a higher rate than expected among some groups of workers.

Why was I contacted about the study? How did you get my name?

The NIEHS worked with other federal agencies, BP contractors, local government agencies, and community groups to develop a combined list of people eligible for this study. You have been contacted because we believe that you may be eligible to participate in the study, either because you worked directly in oil spill clean-up or because you had some other link to the oil spill.

Why are you concerned about health effects if workers had safety training and used protective gear?

Even workers who received training and tried to follow all the guidelines given to them may have had oil spill exposures. Heat and humidity made it hard to follow all of the guidelines. Safety procedures often reduce, but do not fully eliminate, certain exposures. The training and safety procedures were based on what was known at the time of the spill. But there have been few studies about the potential risks of oil spill clean-up. It is very important to study the health of people who did clean-up. This will help identify and concerns for people who were exposed to the oil. It will help officials know what to do if there is another spill.

Will this study identify all diseases that may be associated with the spill?

The goal of this study is to identify diseases related to oil spill clean-up activities. This study will look at a wide range of diseases. We will follow workers for a long time so

that we have a chance of finding out about diseases that take many years to develop. The study is large enough to identify many diseases, even ones that are less common. But it may not be possible to identify diseases that are very rare.

Why would I want to participate in this research study?

Participating in this study will give you a chance to share your experiences during and after the oil spill clean-up. Most people who participate in research hope that it will produce information that will benefit themselves or others. Some people want to help others. In this case, people in the study may want to help public health officials and health care providers better understand the potential health impacts of the oil spill on clean-up workers and local communities. They may want to help researchers and officials plan for how to respond if there are other large oil spills in the future.

Who makes sure this study is safe and scientifically sound?

Research funded by the Federal Government is carefully reviewed and monitored. The NIEHS Institutional Review Board (or IRB) is responsible for making sure the study is safe, ethical, and scientifically sound. The IRB is a diverse group that includes experts in the areas of ethics, law, medicine, and science. In addition, this study has been reviewed by many expert groups, including the Institute of Medicine (see <https://www.iom.edu>), an independent, non-profit group that works outside the government. This group gives unbiased and authoritative advice to decision makers and the public. The input received from the overall review process has been used to improve the study.

How will I find out about study results?

Newsletters describing the progress and findings of the study will be mailed to people in the study every year. These reports will be posted on the study website. Results of the study will be reported in publications that are read by physicians, public health professionals, and scientists. Local, state, and national media groups will also be informed of study findings. We will hold community meetings to report results and send newsletters and reports from the study to interested groups.

What tests will be done with my samples?

All of your samples will be frozen and stored in a secure laboratory. At a later date, we will use your samples for research. We will look for signs of oil exposure and related health effects. We will test samples for a variety of chemicals, hormones, markers of biological changes, and environmental agents. We will also study effects on genes and if genetic factors interact with chemical exposures to increase or decrease the chances of becoming sick. All research tests will not be done on all participants. *We will not test for illegal drugs.*

Will I receive the results of my blood tests and other study procedures?

You will receive a report with results from measurements of your blood pressure, body mass index, and urine glucose (sugar) level. Some results will be given to you at the time of the visit. A report mailed to you within 3 to 4 weeks of the home visit will include results from on lung function (if tested) and any blood tests that are done using your fresh blood samples, such as your blood count. The report will include an explanation of what each test is for. If one of these results suggests you should see a doctor right away, we will tell you during the home visit or call you as soon as we get the results.

Will I receive any other clinically important results?

At this time, the exact number and specific types of tests we will do is not known. Although research tests of samples may reveal clinically useful information, it may be many years before your samples are analyzed. The tests we do for research may not be done in a certified clinical laboratory. Therefore, you should continue to visit your doctor for routine health care. If we discover something that could be clinically useful, we will send you results from tests done in a certified laboratory or we will send you a summary report of study findings that you can share with your doctor. Your doctor can help you decide if further actions or tests are needed.

What should I do if I have questions about my study results?

You should discuss your test results with your doctor. If you do not have a regular doctor, you may call the study center at 1-855-NIH-GULF (1-855-644-4853) to receive a referral to a local health care provider. We will be happy to answer general questions about the tests. You can call the study center with questions. But, your doctor will be in the best position to know what is right for you.

Why do you need my Social Security number?

In order to accurately link to outside records containing information on deaths, cancer, and other diseases, we will ask you to share your Social Security number. Although you will have given other identifying information such as your name and date of birth, especially for common names, the Social Security number is the only factor that is unique to you and will allow us to make sure we get the correct information about changes in your health. We will store your Social Security number in a separate secure file and will not share it with others. If you are still reluctant to share your Social Security number, we will ask you to provide the last 4 digits. This will help match to the correct records even though it does not uniquely identify you.

Why do you need identifying information, like my address, phone number, and date of birth?

During our initial telephone interview, we ask for your address, phone number, and date of birth to verify that we have contacted the right person for the interview. Some participants will be invited to take part in additional study activities after the initial telephone interview, such as home visits, follow-up telephone interviews, and clinical visits. We need contact information to reach participants who take part in those future

activities. We also want to send all participants an annual newsletter to keep them updated about the study.

Will you share my information with my employer or insurance provider?

No. We will not give study information to employers or insurance providers. Privacy rules strictly prohibit sharing information about study participants with these groups. However, you are allowed to share information with your employers and insurance provider. If an insurer or employers learns from you that you are in the study and you consent in writing to have the information shared, we will give out the information. You and your family should actively protect your own privacy.

How will you protect my privacy?

We will make every effort to protect your privacy and keep your data confidential. People in NIH studies are not named in reports or presentations. Furthermore, a law called The Federal Privacy Act protects your information. We will label the information from this interview with a special code number instead of your name so you will not be identified. Only authorized staff will see your private information.

Do you have any additional ways to protect my privacy?

For added protection, the study has a Certificate of Confidentiality which helps us protect the privacy and confidentiality of people in the study. The Certificate helps to prevent us from being forced to give out information that could identify you in a court of law. A Certificate of Confidentiality does not prevent you from giving out information about your own involvement in this study. If you want us to send information about you to a doctor, insurer or employer, you must request this from us in writing.

Data we collect may be shared with other qualified researchers, but we will do everything we can to protect your privacy.

Why do I have to provide the names and telephone numbers of other contacts?

Since this is a long-term study, people in the study may move or change their telephone number and forget to tell us. We want to make sure we will be able to reach you in future years. If we have trouble reaching you, we will call the contacts you've provided to find out where we can reach you. Please select people who will always know where you are in case you move.

What Should I Do If...?

What should I do if I want to find out if the study is legitimate?

You may contact the Public Affairs/Communications Office at the NIEHS at 1-919-541-0073. You may also call the NIEHS Office of Human Research Compliance, at 1-919-541-3852. ***What should I do if I have questions about the study?***

If you have questions about the study, you may call the GuLF STUDY toll-free number, 1-855-NIH-GULF (1-855-644-4853), and ask our staff any questions that you may have. You may also visit the study website at www.nihgulfstudy.org.

What should I do if I decide to participate and change my mind later?

You may withdraw from the study at any time. If you change your mind after you enroll, please call the GuLF STUDY toll-free number, 1-855-NIH-GULF (1-855-644-4853), as soon as possible. Tell us that you no longer want to be in the study.

What if I need to change the time of my home visit or forget the appointment?

Please call the GuLF STUDY toll-free number, 1-855-NIH-GULF (1-855-644-4853), as soon as possible. Tell us the date and time of your original appointment so that we can reschedule the visit.

What if I have a problem or complaint about the telephone interview or in-home visit?

Please call the GuLF STUDY toll-free number, 1-855-NIH-GULF (1-855-644-4853), as soon as possible. Tell us about the problem and the date and time that it occurred. We will relay your concern to the investigators and our study staff. We will take any action that is necessary.